



**UNITED STATES DEPARTMENT OF COMMERCE  
Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/068,253	06/09/98	SHIMURA T	144,123

CHARLES A MUSERLIAN  
BIERMAN MUSERLIAN & LUCAS  
600 THIRD AVENUE  
NEW YORK NY 10016

HM12/0413

MOEZIE, F	EXAMINER
-----------	----------

ART UNIT 1653	PAPER NUMBER
------------------	--------------

DATE MAILED: 04/13/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

*Office Action Summary*

Application No.

09/068,253

Applicant(s)

SHIMURA et al

Examiner

F. T. Moezie

Group Art Unit

1653



☒ Responsive to communication(s) filed on Jan 21, 2000

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

**Disposition of Claims**

☒ Claim(s) 2-5 and 7-12 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 2-5 and 7-12 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

**Application Papers**

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 10

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

FM

Art Unit: 1653

## **DETAILED ACTION**

### **STATUS OF CLAIMS**

Claims 2-5 and 7-12 are pending prosecution in this Office action.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### **NEW GROUNDS OF REJECTION - 35 USC 112, FIRST PARAGRAPH**

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2-5 and 7-12 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The temperature limitation in claim 12 (the only independent claim in this case) constitutes NEW MATTER. Furthermore, the term "agent" is NEW MATTER.

Cancellation of the NEW MATTER is suggested.

### **REJECTION - 35 USC 112, SECOND PARAGRAPH**

Art Unit: 1653

Claims 2-5 and 7-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 12 (upon which all other claims depend) is indefinite and incorrect. The term "a polyoxyethyle-polypropylene glycol" is incorrect, (see the original claim 1). Additionally, "the molecular weight of propylene glycol being 900 to 4000" is incorrect. Perhaps the total molecular weight of the polymer is 900-4000 (see the original claim 2). Finally the term "agent" render the claim indefinite as to what is being claimed. Substitution of "protein " for "agent " is suggested (see the original claim 1).

Claims 2-5 and 7-11 are indefinite because the terms "repairing" or "repairing material" do not find antecedent basis in claim 1 (amended), from which they depend.

Claims 4 and 5 are indefinite because the term "in either" render the claim confusing and is excessive.

Claim 5 and claims dependent thereon are indefinite and confusing because: a) there is no "treating" at line 1 of the claim so that the amended material (the host) could be entered; b) assuming the host is entered following "treatment" on line 1, then the claim language is confusing.

**REJECTION - 35 USC 102/103**

Art Unit: 1653

Claims 2-5 and 12 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over WO 94/1483.

The reference teaches a therapeutic composition comprising a polyoxyethylene-polyoxypropylene (page 3, lines 15-16) and a bone morphogenic protein (page 10, line 33). The composition is in aqueous solution, injectable and remains in liquid form at body temperature (pages 4-5). The molecular weight for the polymer can be adjusted depending on the desired release rate for the active agent (page 9, first paragraph). The claimed subject matter would have been immediately envisaged by an ordinary <sup>skill</sup> ~~person~~ in the art at the time the invention was made given the teachings of the prior art.

Claims 2-5 and 7-12 remains rejected under 35 U.S.C. 103(a) as being unpatentable over WO/1483 A in view of JP 62-135431 or Ron et al for the reasons of record, paper no. 8.

## **RESPONSE TO ARGUMENTS**

The response filed 21 January 2000, paper no. 10, has been considered and found persuasive in-part.

Claim 1 has been deleted and claim 12 has been added. All of the claims have been amended.

Art Unit: 1653

Some of the earlier rejections of the claims under 35 USC 112, second paragraph, is withdrawn in view of the amendment and remarks. However, the rejections as applied herein above are maintained for the reasons cited herein above.

The rejection of claim 1 under 35 USC 102 (b) over WO 94/1483 is withdrawn in view of the amendment to the claims.

However, upon further consideration it appears that given the teachings of the reference one of ordinary skill in the art would immediately envisage the claimed subject matter (claims 2-5 and the newly added claim 12) as explained herein above.

The rejection of claims 2-5 and 7-11 under 35 USC 103 (a) over WO 94/1484 A in view of JP 62- 135431 or Ron et al is maintained for the reasons of record. This ground of rejection is extended to encompass the newly added claim 12.

Applicants' remarks regarding the novelty of the composition (page 4 of remarks) is not well taken for the following reasons;

a) applicant has not clearly and specifically pointed out the bases for the amendatory materials. Furthermore, it appears that the applicant does not adhere to a consistent language for the claim elements - compare the polymers' name in claim 12 and claim 2, for example;

b) Paragraph bridging pages 6 and 7 does NOT cite either the temperature range of "1-30°C" or the "molecular weight of 900-4000" as alleged. Moreover, at page 7, line 13, the "molecular weight of propylene glycol of 3,850 " is erroneous and the number must refer to the poly compound;

Art Unit: 1653

c) Applicants' remarks at page 4, first full paragraph, is confusing as to which reference is being discussed since the document(s) being discussed are not identified and

d) Because applicant does not clearly point out where in the rejection discrepancies or errors may exist, the rejection is found proper and maintained.

### **PRIOR ART**

The prior art submitted by the applicant has been placed in the file. However, because the Examiner has not been able to obtain either an English equivalent or an English language translation of the submitted art, the Japanese references have not been considered on their merits. Applicant is requested to submit an English language abstract of the documents for consideration by the Examiner.

### **CONCLUSION**

No claims are allowed

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO**

Art Unit: 1653

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication should be directed to F. T. Moezie at telephone number (703) 305-4508 or Mr. LOW (SPE) at 308-2923.

*F. T. Moezie*  
F. T. MOEZIE, PH.  
PRIMARY EXAMINE  
ART UNIT 1653